UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. GENENTECH, INC., Defendant.	Civil Action No. 10-CV-08779 (JFM) (PED) ECF Case

GENENTECH'S MEMORANDUM OF LAW IN SUPPORT OF ITS MOTION TO DISMISS THE COMPLAINT FOR LACK OF SUBJECT MATTER JURISDICTION

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Defendant Genentech, Inc. ("Genentech") respectfully submits this memorandum of law in support of its motion to dismiss the complaint of Plaintiff Regeneron Pharmaceuticals, Inc. ("Regeneron").

PRELIMINARY STATEMENT

Regeneron asks this Court to declare that no activities related to its product "VEGF Trap" infringe any valid claim of five of Genentech's patents. But Regeneron has yet to commercialize -- or even to seek Food and Drug Administration ("FDA") approval to commercialize -- VEGF Trap, and Genentech has taken no affirmative act against Regeneron. As a matter of law, then, there is no justiciable controversy here.

In its 2007 *MedImmune* decision, the Supreme Court held that declaratory judgment actions in patent cases are justiciable only where there is "a substantial controversy" between the parties "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 126 (2007) (quoting *Md. Cas. Co.* v *Pac. Coal & Oil Co.*, 312 U.S. 270 (1941)). The dispute may not be hypothetical or premature; it must be "definite and concrete," it must be "real and substantial," and it must "admit of specific relief through a decree of conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Id.*

Regeneron's complaint is exactly the hypothetical exercise that *MedImmune* prohibits, for two reasons:

First, Regeneron has not alleged that it has taken any action that would give rise to a patent infringement claim. It alleges only that VEGF Trap is "currently in late stage clinical development," and that "a large number of additional clinical trials are

ongoing or planned for the VEGF Trap." (Cmplt. ¶¶ 4, 14, attached hereto as Gallo Decl. Ex. 1.) Clinical trials are shielded from patent infringement lawsuits by the "safe harbor" of 35 U.S.C. § 271(e)(1), which applies to use of patented products "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products." And while Regeneron alleges, conclusorily, that "concrete and substantial steps have been taken to prepare for commercial manufacturing and marketing of the VEGF Trap," it does not allege any details at all about those steps or whether they, too, fall within the safe harbor. (Cmplt. ¶ 12.) Just as Genentech could not sue Regeneron for infringement based on safe-harbor-protected conduct, Regeneron cannot seek a declaratory judgment of non-infringement based on only that same protected conduct. *See, e.g., W.L. Gore & Assocs., Inc.* v. *GI Dynamics, Inc.*, No. CV-10-8088, 2010 WL 5184254 at *6 (D. Ariz. Dec. 15, 2010).

Even without the safe harbor, Regeneron has not alleged that VEGF Trap is far enough along in its development to create a controversy "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 549 U.S. at 126. It does not allege that it has requested or received Food & Drug Administration approval of VEGF Trap and is poised to sell. Instead, Regeneron alleges only that it "intends" to submit a Biologics License Application ("BLA") to the FDA, a prerequisite for sale of VEGF Trap, "before the end of the second quarter of 2011" – *i.e.*, by the beginning of July. (Cmplt. ¶ 11.) Regeneron may choose not to file that application based on the results of its still-ongoing clinical studies. If Regeneron files a BLA, the FDA may reject it, or require additional information. Regeneron admits this in its public

filings: "[i]t is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses." (Gallo Decl. Ex. 2, Regeneron Form 10-Q Sept. 30, 2010 at 29.) Or the FDA might require Regeneron to make changes to VEGF Trap, its formulation, or the medical conditions for which it is indicated. It takes, on average, six months for the FDA to approve a BLA if fast-track review is granted -- fifteen months without fast-track review -- and approximately 25% of fast-track, and 69% of non-fast-track applications, are not approved in their first review cycle. (Gallo Decl. Ex. 3.) On Regeneron's stated schedule, VEGF Trap might not get FDA approval until late 2011 or 2012, if ever. Right now, there is no justiciable controversy.

Second, and relatedly, Regeneron has alleged no affirmative act by Genentech, a prerequisite to suit under post-*MedImmune* case law. The Complaint does not allege that Genentech sent Regeneron a cease-and-desist letter or otherwise warned Regeneron that VEGF Trap violates its patents, that Genentech threatened suit, or that Genentech has requested a license agreement for VEGF Trap. The Complaint does not allege that Regeneron sought a license for the patents and was rebuffed. It does not even allege that Genentech and Regeneron have communicated at all. The sole allegation about Genentech's conduct regarding VEGF Trap is based on unspecified information, and attributes vaguely described sentiments to unnamed people:

> Regeneron is informed and believes, and thereon alleges, that Genentech has indicated, among other things, that Regeneron's VEGF Trap will not have freedom to operate based on [Genentech's] Davis-Smyth Patents and referred to Regeneron's discussion of the threat of the Davis-Smyth Patents in its [*i.e.*, Regeneron's own] SEC filings.

(Complaint ¶ 17.) This raises more questions than it answers. Who informed Regeneron of this? Someone from Genentech? If so, who at Genentech "referred to" Regeneron's

SEC filings? What did that person say? To whom?

To be clear, these questions do not represent only a failure of pleading. They confirm that this Court lacks jurisdiction to hear this case. In post-*MedImmune* declaratory judgment actions where courts have found ripe controversies under Article III, the patent owner "has either demonstrated a preparedness to litigate against the prospective declaratory judgment plaintiff, accused the prospective declaratory judgment plaintiff of infringement, affirmatively asserted its rights to license fees, or engaged in some combination of all three." *Geospan Corp.* v. *Pictometry Int'l Corp.*, 598 F. Supp. 2d 968, 970 (D. Minn. 2008). Genentech has done none of them.

That is not to say that Genentech will never assert patent rights against Regeneron. It might well. But Regeneron has jumped the gun. It does not yet have a commercial product or process, it has not even sought a Biologics License Application, and it may never seek or receive a license. Should VEGF Trap approach commercial viability, Genentech will take whatever actions it deems appropriate to protect its interests, including its intellectual property, and Regeneron can govern itself accordingly or seek judicial relief as it believes warranted. Right now, however, the Court lacks jurisdiction to hear Regeneron's claims, as they are not yet ripe. The Court should dismiss this case without prejudice.

STATEMENT OF FACTS

The following facts are set forth in Regeneron's Complaint, its public filings with the Securities & Exchange Commission, and the accompanying declaration of Kenneth A. Gallo and the exhibits thereto.

Wet Age-Related Macular Degeneration and VEGF

This case relates to products that bind to Vascular Endothelial Growth Factor ("VEGF"). VEGF is a protein that stimulates the growth of new blood vessels, a process called "angiogenesis." In healthy people, cells produce VEGF to, among other things, assist creation of new blood vessels, re-populate blood vessels after injury, and grow new blood vessels to bypass damaged ones. (Gallo Decl. Ex. 4 at 5.)[1]

VEGF can play a role in harmful pathologies as well, however. For example, tumors express VEGF to stimulate blood vessel growth, allowing the tumors to grow and to metastasize. VEGF also contributes to diseases and conditions caused by a proliferation of unwanted blood vessels. (Gallo Decl. Ex. 4 at 5.) These include Neovascular Age-Related Macular Degeneration, which causes decreased eyesight in older people. Neovascular, or "Wet," AMD is characterized by growth of new blood vessels behind the retina, under the central portion called the macula. These new blood vessels tend to leak blood and other fluids, dislocating the macula and causing vision loss. (Gallo Decl. Ex. 5.) VEGF also plays a role in Central Retinal Vein Occlusion, "CRVO," a condition in which the central vein that supplies blood to the retina becomes blocked, causing blood and other fluid to pool in the retina, decreasing vision. Occlusion of the central vein can also cause the retina to become starved for blood, which in turn causes the growth of new, abnormal blood vessels, which in turn leak blood and fluid and compound the vision loss. (Gallo Decl. Ex. 5.)

Genentech has been a pioneer in researching and developing treatments to inhibit the unwanted effects of VEGF, including treatments for cancer, for Wet AMD,

and for CRVO. Particularly relevant to this case are Genentech's efforts to treat eye disease. Specifically, Genentech received FDA approval for an anti-VEGF drug, Ranibizumab, marketed as "Lucentis." A VEGF inhibitor, Lucentis is approved for treatment of Wet AMD and for CRVO. (Gallo Decl. Ex. 4 at 2-3.)

Regeneron and VEGF Trap

Regeneron alleges that its "scientists discovered a novel biopharmaceutical" that it calls the VEGF Trap. (Cmplt. ¶¶ 3-4.) The VEGF Trap is being studied, Regeneron alleges, in connection with Wet Age-Related Macular Degeneration. (*Id.* ¶ 11.) Its website touts that VEGF Trap is also being studied for CRVO. (Gallo Decl. Ex. 5.)

Like Lucentis, VEGF Trap is a "biologic," a product created by biological processes rather than through chemistry. Biologics comprise vaccines, blood and blood components, tissues, and a wide range of other products. A manufacturer must obtain a license before selling a biologic in interstate commerce. *See* 42 U.S.C. § 262. To obtain a license, the manufacturer must file a "Biologics License Application" with the FDA, providing clinical and laboratory data demonstrating "that the manufactured product meets prescribed requirements of safety, purity, and potency." *See* 21 C.F.R. 601.2. The process can be slow, even assuming that the biologic is ultimately approved: While the FDA can "fast track" the review of products that "demonstrate[] the potential to address unmet medical needs" for "serious or life threatening conditions," 21 U.S.C. § 356(a)(1), published data show that fast-track approval of a BLA takes, on average, six months, and approximately 25% of these fast-track applications are not approved in their first review

[1] Regeneron's Complaint does not explain what VEGF is, or what its proposed product,

cycle. (Gallo Decl. Ex. 3.) Non-expedited review takes 15.1 months to approval, with a mere 31% of applications approved in their first review. (*Id.*) The FDA can also require the applicant to modify aspects of its product or manufacturing process, lengthening the time to approval.

Regeneron has not yet filed a BLA. Regeneron alleges only that the VEGF Trap is "currently in late stage clinical development," that "a large number of additional clinical trials are ongoing or planned for the VEGF Trap," and that "Regeneron intends to submit a Biologics License Application" to the FDA "before the end of the second quarter of 2011." (*Id.* ¶¶ 4, 11, 14.)

In its public filings with the Securities and Exchange Commission, Regeneron discloses the risk that the FDA might reject its Biologics License Application, or that the process might move more slowly than Regeneron expects:

> Following successful completion of Phase 3 clinical trials for a biological product, a biologics license application (or BLA) must be submitted to, and accepted by, the FDA, and the FDA must approve the BLA prior to commercialization of the drug. It is not uncommon for the FDA to request additional data following its review of a BLA, which can significantly increase the drug development timeline and expenses.

(Gallo Decl. Ex. 2, Regeneron Form 10-Q Sept. 30, 2010 at 29; Ex. 6, Regeneron Form 10-Q March 31, 2010 at 28; Ex. 7, Regeneron Form 10-Q June 30, 2010 at 28.)[2]

Regeneron also disclosed additional risks that might derail or delay its ability to secure approval of and to market VEGF Trap for Wet AMD. These include

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VEGF Trap, does. We provide this summary for the Court's convenience.

[2] This Court may consider Regeneron's public filings on a motion to dismiss for lack of subject matter jurisdiction, *Roth* v. *Jennings*, 489 F.3d 499, 509 (2d Cir. 2007), and because Regeneron itself referred to its public filings in its Complaint, *Rothman* v. *Gregor*, 220 F.3d 81, 88-89 (2d Cir. 2000).

financial risks: "Our expenses may increase for many reasons," including expenses "related to new clinical trials" for VEGF Trap. "We may require additional financing in the future and we may not be able to raise such additional funds." (Gallo Decl. Ex. 2, Regeneron Form 10-Q Sept. 30, 2010 at 39.) And these include commercial risks. Regeneron is developing VEGF Trap for ocular diseases in cooperation with Bayer HealthCare, and is thus exposed to (and has disclosed) the risk that Bayer may terminate the arrangement or not honor its commitments: "If our collaboration with Bayer HealthCare for VEGF Trap-Eye is terminated, or Bayer HealthCare materially breaches its obligations thereunder, our business operations and financial condition, and our ability to develop and commercialize VEGF Trap-Eye in the time expected, or at all, would be materially harmed." (*Id.* at 48.)

The Complaint, this Action, and Regeneron's Post-Complaint Overture

Regeneron filed its Complaint on November 19, 2010. It seeks a declaration that Regeneron's activities with respect to VEGF Trap do not infringe any valid claim of five patents held by Genentech, which the Complaint refers to as the "Genentech Davis-Smyth Patents." (Cmplt. ¶ 2, *see also id.* at ¶¶ 15-18.)

The Complaint is only five pages long, and is most notable for what is missing. It does not allege that Genentech has sent a cease-and-desist letter to Regeneron. It does not allege that Genentech has threatened Regeneron with suit. It does not allege that Genentech has insisted or even asked that Regeneron take a license for any of Genentech's patents in order to market VEGF Trap. It does not allege that Genentech rejected a license request from Regeneron, or that Regeneron made such a request.

Indeed, the Complaint does not allege any conversations or communications between Regeneron and Genentech about VEGF Trap at all.

Although the Complaint alleges, *ipse dixit*, that "Genentech's conduct with regard to VEGF Trap creates a substantial controversy between Regeneron and Genentech with respect to the VEGF Trap of sufficient immediacy and reality to warrant the issuance of a declaratory judgment," it accompanies that boilerplate statement with only one alleged act of "conduct" by Genentech, based on only information and belief:

> Regeneron is informed and believes, and thereon alleges, that Genentech has indicated, among other things, that Regeneron's VEGF Trap will not have freedom to operate based on Davis-Smyth Patents and referred to Regeneron's discussion of the threat of the Davis-Smyth Patents in its SEC filings.

(Cmplt ¶ 17.) Context makes clear that "in its SEC filings" refers not to Genentech's SEC filings, but to Regeneron's own SEC filings. In the preceding paragraph of the Complaint, Regeneron alleges that in its own SEC filings it disclosed the existence of the Genentech Davis-Smyth Patents and the possibility that "Genentech could initiate a lawsuit for patent infringement" over VEGF Trap. (Cmplt. ¶ 16.) Thus, in paragraph 17, Regeneron alleges that it has been "informed," by an unnamed person, that "Genentech has indicated," to an unnamed person, "that Regeneron's VEGF Trap will not have freedom to operate" based on Genentech's patents, and that some unnamed person at Genentech has "referred to" Regeneron's own SEC filings. To whom that person spoke and what he or she said is unexplained.

On that thin reed, Regeneron sought to invoke this Court's declaratory judgment jurisdiction. Then, more than a month after it filed the Complaint, Regeneron wrote to Genentech, stating that Regeneron "took the step of filing this suit in order to confirm that Genentech has no rights in and cannot block patient access to VEGF Trap,"

and asking Genentech to agree not to assert its patents against Regeneron. (Gallo Decl. Ex. 8.)

Genentech now moves to dismiss the Complaint without prejudice for lack of subject matter jurisdiction.

ARGUMENT

As this case confirms, declaratory judgment actions create the risk of abusive litigation. Litigants may "misuse the declaratory judgment remedy as a means to . . . gain leverage in their private interactions before any concrete claim arises." 15 JAMES WM. MOORE ET. AL., MOORE'S FEDERAL PRACTICE § 101.80[2] (3d ed. 1999). That is why the Declaratory Judgment Act permits a federal court to declare the rights of the parties only "[i]n a case *of actual controversy* within its jurisdiction." 28 U.S.C. § 2201(a) (emphasis added), embodying the Article III limitation that federal courts have jurisdiction to hear only "cases and controversies." *See generally SanDisk Corp.* v. *STMicroelectronics, Inc.*, 480 F.3d 1372, 1378 (Fed. Cir. 2007). And that is why the burden of proving jurisdiction rests with the party bringing the declaratory judgment action, Regeneron. *See Benitec Australia, Ltd.* v. *Nucleonics, Inc.*, 495 F.3d 1340, 1344 (Fed. Cir. 2007).

In *MedImmune*, the Supreme Court set the standard that Regeneron must meet, requiring the declaratory judgment plaintiff in a patent case to demonstrate that the dispute is "definite and concrete, touching the legal relations of parties having adverse legal interests," that the dispute is "real and substantial," and that it "admit[s] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *MedImmune, Inc.* v. *Genentech, Inc.*, 549 U.S. 118, 127 (2007) (quotation omitted). In short, the Court

instructed, the question "'is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Id.* (*quoting Md. Cas. Co.* v. *Pac. Coal & Oil Co.*, 312 U.S. 270, 273 (1941)).

The court determines whether a justiciable controversy existed at the time the Complaint was filed, without regard to subsequent events. *See, e.g., Innovative Therapies, Inc.* v. *Kinetic Concepts, Inc.*, 599 F.3d 1377, 1383-1384 (Fed. Cir. 2010).

As we show below, Regeneron has not alleged facts showing a "definite and concrete" dispute between it and Genentech about VEGF Trap.

I.

THERE IS NO JUSTICIABLE CONTROVERSY HERE BECAUSE REGENERON HAS NOT SOUGHT REGULATORY APPROVAL TO COMMERCIALIZE VEGF TRAP

Regeneron admits, in its Complaint, that it has not yet sought regulatory approval to commercialize VEGF Trap, and may not do so for many months, if ever. In its public filings, Regeneron also admits that even assuming it seeks regulatory approval, the FDA could reject its application, as happens often, or insist that Regeneron conduct additional testing or take other actions that will substantially prolong the approval process. Any dispute between Genentech and Regeneron about VEGF Trap is therefore not "of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune, Inc.*, 549 U.S. at 127.

Indeed, the patent laws shield the use of patented products to provide information to the FDA about drugs, medical devices, or biologics. Under the so-called "safe harbor" of 35 U.S.C. § 271(e)(1), it is not an act of patent infringement to make or

use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."[3] And just as a patent owner cannot sue an infringer for conduct shielded by the safe harbor, so too an infringer cannot sue the patent owner for a declaratory judgment of non-infringement about only that same conduct. Thus, in a post-*MedImmune* decision, the Federal Circuit observed that in a declaratory judgment action, "[a] useful question to ask in determining whether an actual controversy exists is what, if any, cause of action the declaratory judgment defendant may have against the declaratory judgment plaintiff." *Benitec Australia, Ltd.*, 495 F.3d at 1344.

Under *Benitec*, in deciding whether Regeneron's declaratory judgment action presents a justiciable controversy, the Court may ask whether Genentech could have sued Regeneron based on the conduct alleged in the declaratory judgment complaint. While Regeneron asserts without explanation that "concrete and substantial steps have been taken to prepare for commercial manufacturing and marketing of the VEGF Trap," (Cmplt. ¶ 12), the only actual facts pleaded in the Complaint are that VEGF Trap is "currently in late stage clinical development," and that "a large number of

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[3] 35 U.S.C. § 271(e)(1) provides in full:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

additional clinical trials are ongoing or planned for the VEGF Trap." (Cmplt. ¶¶ 4, 14.) Clinical trials are shielded by the safe-harbor provision. Just as they could not support a claim by Genentech against Regeneron, they also cannot create jurisdiction for Regeneron's declaratory judgment action against Genentech. *See, e.g., W.L. Gore & Assocs., Inc.* v. *GI Dynamics, Inc.*, No. CV-10-8088, 2010 WL 5184254, at *6 (D. Ariz. Dec. 15, 2010).

Even without regard to the safe harbor, Regeneron has not taken steps to commercialize VEGF Trap sufficient to render justiciable disputes about whether VEGF Trap and its related processes infringe Genentech's patents under the *MedImmune* standard. Regeneron "intends" to submit a Biologics License Application to the FDA only "before the end of the second quarter of 2011." (Cmplt. ¶ 11.) As Regeneron has admitted in its public filings, the FDA could reject Regeneron's BLA, or it could ask for more information or more testing, slowing down the approval process. (Gallo Decl. Ex. 2, Regeneron Form 10-Q Sept. 30, 2010 at 29; *see also id.* Ex. 6, Regeneron Form 10-Q March 30, 2010 at 28; Ex. 7, Regeneron Form 10-Q June 30, 2010 at 28.) If Regeneron files its BLA in July of this year, FDA approval could occur later this year, or in 2012. (Gallo Decl. Ex. 3 at 1.)

Because the FDA approval process can compel significant changes in a proposed product, courts have considered the possibility of such changes in determining whether a patent controversy was ripe for adjudication. In *Telectronics*, for example, the Federal Circuit noted that a case could lack "sufficient immediacy and reality to meet the actual controversy requirement under the Declaratory Judgment Act" where a product was still being approved by the FDA and there "was no certainty that the device when

approved would be the same device that began clinical trials." *Telectronics Pacing Sys. Inc.* v. *Ventritex, Inc.*, 982 F.2d 1520, 1527 (Fed. Cir. 1992). And courts have found that declaratory judgment claims were not ripe where the applicants had not yet filed for FDA approval. *See, e.g., Benitec Australia, Ltd.*, 495 F.3d 1346-47; *see also Shaunnessy* v. *Monteris Medical, Inc.*, 554 F. Supp. 2d 1321, 1324, 1329 (M.D. Fl. 2008).

So, too, here. At least until Regeneron files a Biologics License Application, no one -- not Regeneron, not Genentech, and not the Court -- can determine whether litigation between Regeneron and Genentech will be necessary. By filing suit now, Regeneron has asked this Court to exceed its jurisdiction.

II.

THERE IS NO JUSTICIABLE CONTROVERSY HERE BECAUSE REGENERON HAS NOT ALLEGED ANY AFFIRMATIVE ACT BY GENENTECH

There is a second, related reason that the Complaint should be dismissed: Declaratory judgment jurisdiction "will not arise . . . without some affirmative act by the patentee." *Sandisk Corp.* v. *STMicroelectronics Inc*, 480 F.3d 1372, 1381 (Fed. Cir. 2007). Thus, in the post-*MedImmune* cases finding a case or controversy, "a patentee has either demonstrated a preparedness to litigate against the prospective declaratory judgment plaintiff, accused the prospective declaratory judgment plaintiff of infringement, affirmatively asserted its rights to license fees, or engaged in some combination of all three." *Geospan Corp*. v. *Pictometry Int'l Corp.*, 598 F. Supp. 2d 968, 970 (D. Minn. 2008).

Regeneron has not alleged that Genentech has done any of these things. And, to be clear, this is not a pleading failure: Genentech *has not* done any of these

things. That is no surprise, given that Regeneron's conduct to date appears shielded by the FDA safe harbor, and that Regeneron has not yet even filed a BLA for VEGF Trap.

Instead, all that Regeneron has done is allege its own belief that Genentech may sue, and allege its own belief that Regeneron would prevail in that suit. That self-supporting, factually bereft allegation failed to support declaratory judgment jurisdiction in *Prasco, LLC* v. *Medicis Pharm. Corp.*, 537 F.3d 1329, 1338-40 (Fed. Cir. 2008). There, too, the potential infringer, Prasco, could not allege any communication or affirmative act by the patentee, Medicis. The Federal Circuit found most telling "that which has *not* occurred":

> the defendants have not accused Prasco of infringement or asserted any rights to OSCION™, nor have they taken any actions which imply such claims. Instead, all we have before us is Prasco's allegation that its product does not infringe the defendants' patents.

Id. at 1340. The court affirmed the dismissal of the case for want of jurisdiction.

Geospan, too, is illustrative: There, the patentee, Pictometry, had not "demonstrated an intent to litigate against Geospan," had not "accused Geospan of infringement," and had not "demanded licensing fees." 598 F. Supp. 2d at 971. There was "no evidence that Pictometry [had] pursued litigation against Geospan." *Id.* Moreover, "Pictometry [had] not yet established *any* position on whether Geospan infringes the '356 Patent." *Id*. The Court found that "there is no substantial controversy regarding the '356 Patent" supporting declaratory judgment jurisdiction. *Id.*

Also instructive is the Federal Circuit's recent decision in *Innovative Therapies, Inc.*, 599 F.3d 1377. Like Regeneron, plaintiff Innovative Therapies relied on its own statements of possible infringement, not on any statement by the patentee, defendant Kinetic Concepts. Specifically, Innovative Therapies relied on its own prior

statements to the FDA that its proposed medical device had the "same technological characteristics" as devices made by Kinetic Concepts. Innovative Therapies also relied on prior lawsuits brought by Kinetic Concepts against *other* competitors for infringement involving similar products. *Id*. at 1381-82. The Federal Circuit rejected plaintiff's own statements to the FDA as a basis for finding an Article III controversy. It also rejected Kinetic Concepts' litigation history, because the mere fact of having sued other companies "does not, in the absence of any act directed toward [plaintiff Innovative Therapies], meet the minimum standard discussed in *MedImmune*." *Id*. at 1382.

The cases that **have** found a ripe controversy also confirm, by counter-example, why this case should be dismissed. Some cases have involved specific threats to sue. For example, in *Micron Tech., Inc.* v. *MOSAID Techs., Inc.*, the patentee, MOSAID, disclosed in its annual report that it believed all of its competitors were infringing its patents, announced on an analyst call that it would be "unrelenting" in asserting its patents against competitors, and sent warning letters to plaintiff Micron strongly suggesting that Micron enter into a license agreement with MOSAID. *Micron Tech., Inc.* v. *MOSAID Techs., Inc.*, 518 F.3d 897, 899-900 (Fed. Cir. 2008). Other cases have found a heightened likelihood of future ripe controversies where the parties have sued each other in the past. *See, e.g., Astec Am., Inc.* v. *Power-One, Inc.*, No. 6:07-cv-464, 2008 WL 1734833, at *5-7 (E.D. Tex. April 11, 2008); *Cimline, Inc.* v. *Crafco, Inc.*, Civ. No. 07-3997, 2007 WL 4591957, at *4 (D. Minn. Dec. 28, 2007).

Against this case law, Regeneron's barebones Complaint cannot support jurisdiction. As in *Innovative Therapies*, Regeneron trumpets only its own public filings announcing the existence of Genentech's patents. As in *Geospan* and *Prasco*, Regeneron

cannot allege that Genentech has threatened Regeneron, demanded license fees, or even spoken to anyone at Regeneron. The sole factual allegation, cloaked in anonymity and vagueness, is that Regeneron has heard that someone at Genentech "indicated" that "VEGF Trap will not have freedom to operate" based on Genentech's patents. (Cmplt. ¶ 17.) That is a far cry from the affirmative act by the patentee that the post-*MedImmune* case law requires. And Regeneron's failing is brought into even sharper relief by its resort to "information and belief" to qualify the allegations in paragraph 17. Although a complaint may contain allegations made on information and belief, "it is axiomatic that the complaint must allege facts demonstrating the basis for the information and belief." *MLSMK Inv. Co.* v. *JP Morgan Chase & Co.*, No. 09 Civ. 4049, 2010 WL 2925403, at *5 (S.D.N.Y. July 15, 2010) (quotation omitted). At this, too, Regeneron has failed.

Nor can Regeneron cure its jurisdictional failing by prodding Genentech with a letter four weeks *after* Regeneron filed suit. (Gallo Decl. Ex. 8.) Jurisdiction is determined at the time the Complaint is filed, and Regeneron's effort to draw Genentech into a dispute confirms only that there was no dispute at the time the Complaint was filed. *See, e.g., Innovative Therapies, Inc.*, 599 F.3d at 1383-84.

Without any allegation of an affirmative act by Genentech, this action should be dismissed.

CONCLUSION

For the reasons stated herein, Genentech respectfully asks the Court to dismiss this action without prejudice for lack of subject matter jurisdiction.

Dated: January 11, 2011
Washington, DC

Respectfully submitted,

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